K120543

CardiacAssist, Inc.

MAY 30 2012

510(k) Summary

Date: May 17, 2012

Applicant

CardiacAssist, Inc.
240 Alpha Drive
Pittsburgh, PA 15238
Telephone: 412-963-7770
Fax: 412-963-0800

Contact person

Katie Dillon
Title: Regulatory Affairs Manager
Phone: 412-963-7770 x266
e-mail: kdillon@cardiacassist.com

Device

Trade/Proprietary Name:	TandemHeart Femoral Arterial Cannula Set
Common Name:	Femoral Arterial Cannula and Introducer
Classification Name:	Cardiopulmonary bypass vascular catheter, cannula, or tubing. (21 CFR 870.4210, Product Code DWF)

Predicate Device

Medtronic Bio-Medicus Femoral Cannula and Introducer (K924642)

Device Description

The TandemHeart Femoral Arterial Cannula Set consists of two components, as shown in Figure 1: a 17 Fr. Femoral Arterial Cannula and a 12 Fr. Introducer. The device is intended to cannulate vessels, perfuse vessels or organs, and/or connect with accessory extracorporeal circulatory support equipment. The product is intended to be single patient, single use, sterile device.

The cannula has multiple side holes in addition to the tip opening for unimpeded flow of blood at the distal end and a vented barbed fitting at the proximal end to enable the connection of 3/8" tubing. Radiopaque markers are embedded at the distal tip of the cannula, and the cannula body is wire-reinforced for visualization under fluoroscopy. Insertion depth markings have been incorporated in the cannula body working length from 5 to 17 cm measured from the distal tip.

The cannula includes a suture wing to provide a means for securing the cannula to the patient and a stop component to minimize cannula insertion depth beyond its working length. Printing on the proximal region of the cannula indicates the area where a clamp should be applied if needed during the set-up or removal process.

The 12 Fr. introducer is provided to facilitate placement of the arterial cannula, within the target vessel, and is designed with a tapered distal tip. The introducer proximal end contains a luer hub to aid in the removal of the introducer. The introducer body is also constructed of a radiopaque material for visualization under fluoroscopy.

The introducer includes a hemostasis cap that provides the interface between the cannula proximal connector and introducer body. The hemostasis cap aids in minimizing blood loss during the insertion of the cannula/introducer assembly into the target vessel.

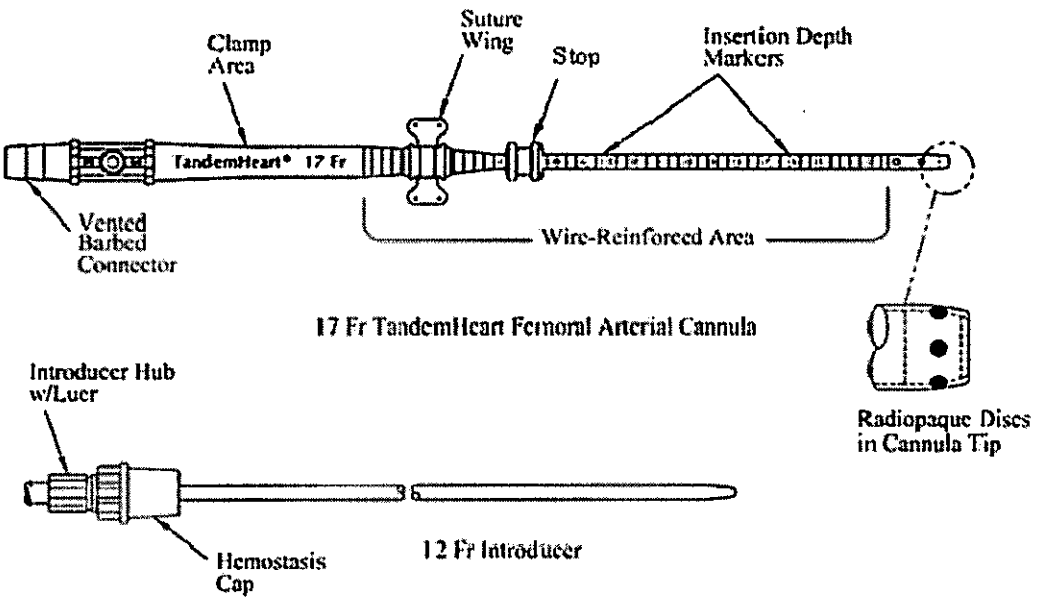


Figure 1: TandemHeart Femoral Arterial Cannula Set

Intended Use

The Femoral Arterial Cannula and Introducer Set is intended to cannulate vessels, perfuse vessels or organs and/or connect with accessory extracorporeal circulatory support equipment for a duration of six hours or less. The cannula introducer is intended to facilitate proper insertion and placement of the cannula within the vessel for extracorporeal circulatory support. These devices are to be used by a trained physician only.

Comparison of Technological Characteristics

The TandemHeart Femoral Arterial Cannula Set and the predicate Medtronic Bio-Medicus Femoral Cannula and Introducer have the same intended use and both consist of a wire-reinforced, polyurethane arterial cannula and a polyurethane introducer. The TandemHeart Femoral Arterial Cannula Set contains two additional components located on the exterior proximal portion of the cannula: a suture wing to provide a means of securing the cannula to the patient and a stop component to minimize insertion of the cannula beyond its working length. The suture wing and stop component are constructed of soft durometer Tecoflex polyurethane, a commonly used material for interventional medical devices, and were tested for biocompatibility. The TandemHeart Femoral Arterial Cannula Set's cannula includes a distal tip taper, while the predicate has a straight tip. The TandemHeart Arterial cannula also has fewer side holes than the predicate device.

Performance Data

Non-clinical performance testing was performed to demonstrate substantial equivalence. The performance testing included in-vitro hemolysis testing, in-vitro system capacity testing, flow vs. pressure drop (HQ), kink testing, leak testing, and deflection testing. All performance tests were conducted on both the TandemHeart Femoral Arterial Cannula Set and the predicate Medtronic Bio-Medicus Femoral Cannula and Introducer. Based on the performance test results, the TandemHeart Femoral Arterial Cannula Set was found to meet the established design input requirements as well as perform substantially equivalent to the predicate Medtronic Bio-Medicus Femoral Cannula and Introducer.

Conclusions

The TandemHeart Femoral Arterial Cannula Set is substantially equivalent to the Medtronic Bio-Medicus Femoral Cannula and Introducer in design characteristics, performance, and intended use. The performance testing demonstrated that despite the geometric differences, including a distal tip taper on the TandemHeart device and fewer side holes than the predicate device, the TandemHeart Femoral Arterial Cannula Set performed substantially equivalent to the predicate device. The two additional components on the TandemHeart Femoral Arterial Cannula Set's cannula body, the suture wing and stop, were found to be biocompatible.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 3 0 2012

CardiacAssist, Inc.
c/o Ms. Katie Dillon
Regulatory Affairs Specialist
240 Alpha Drive
Pittsburgh, PA 15238

Re: K120543
Trade/Device Name: TandemHeart Femoral Arterial Cannula Set
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulatory Class: Class II
Product Code: DWF
Dated: May 17, 2012
Received: May 18, 2012

Dear Ms. Dillon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

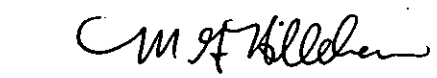
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CardiacAssist, Inc.

Indications for Use

510(k) Number: K120543

Device Name: TandemHeart Femoral Arterial Cannula Set

Indications for Use:

The Femoral Arterial Cannula and Introducer is intended to cannulate vessels, perfuse vessels or organs and/or connect with accessory extracorporeal circulatory support equipment for a duration of six hours or less. The cannula introducer is intended to facilitate proper insertion and placement of the cannula within the vessel for extracorporeal circulatory support. These devices are to be used by a trained physician only.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120543